pharmacological satisfaction while reducing tar deliveries. These product research and development efforts cover a wide variety of strategies to enhance nicotine deliveries, including the use of nicotine-rich tobacco blends, genetic manipulation of tobacco plants, chemical manipulation of tobacco blends, and novel filter designs.

Product Research and Development in the 1960's. BATCO's product i. research and development efforts to optimize nicotine delivery in the 1960's focused on three areas. According to an internal Brown & Williamson memorandum written in 1965, one goal of BATCO research was to "find ways of obtaining maximum nicotine for minimum tar."621 The approaches then under consideration for maximizing nicotine and minimizing tar included "alteration of blends," "addition of nicotine containing powders to tobacco," and "nicotine fortification of cigarette papers." Similarly, at a 1967 BATCO conference, the researchers urged that "[t]he development of low TPM, normal nicotine cigarettes should continue."623

As part of its effort in the 1960's to maximize nicotine while minimizing tar, BATCO investigated whether nicotine delivery could be controlled by increasing the proportion of "extractable nicotine" (also known as "free nicotine") in the smoke through increases in the alkalinity or pH of tobacco smoke. By changing the chemical characteristics of the smoke, this technique would increase the amount of nicotine

⁶²¹ Griffith RB (Brown & Williamson), Report to Executive Committee (Jul. 1, 1965), at 2 (emphasis added). See AR (Vol. 27 Ref. 377).

⁶²³ Minutes of BATCO Group R&D Conference at Montreal, Canada (Oct. 25, 1967), at 4 (emphasis added). See AR (Vol. 27 Ref. 378-1). A "low TPM" cigarette refers to a cigarette low in "total particulate matter" or "tar."

absorbed by the smoker without raising the level of nicotine in the cigarette. A 1966 BATCO study confirmed that "the reaction of a smoker to the strength of the smoke from a cigarette could be correlated to the amount of 'extractable' nicotine in the smoke, rather than to the total nicotine content," further explaining that "it would appear that the increased smoker response is associated with nicotine reaching the brain more quickly." A 1967 BATCO study found that the addition of PEI (polyethyleneimine) to filters caused a significant increase in the delivery of "extractable nicotine" to the smoker. And a 1968 study reported a direct correlation between smoke pH and nicotine absorption in the mouth, stating that "[n]icotine retention appears to be dependent principally on smoke pH and nicotine content." 626

BATCO's second objective was to develop an alternative tobacco product that delivered nicotine but not tar. In the 1960's, BATCO's Charles Ellis worked on Project ARIEL, an early Premier-like tobacco product that involved heating rather than burning nicotine-enriched tobacco. According to a 1967 patent, "the invention . . . seeks primarily to furnish a smoking device which will yield nicotine in an acceptable form, both psychologically and physiologically, but without the necessity for taking into the system so much of the products of combustion as is usual when smoking a conventional

⁶²⁴ BATCO, Further Work on 'Extractable' Nicotine (Sep. 30,1966), at BW-W2-11617 (emphasis added). See AR (Vol. 62 Ref. 308).

⁶²⁵ BATCO, Relation between 'Extractable Nicotine' Content of Smoke and Panel Response (Mar. 17, 1967), at 2. See AR (Vol. 176 Ref. 2045).

⁶²⁶ BATCO, The Retention of Nicotine and Phenols in the Human Mouth (1968), at BW-W2-11691 (emphasis added). See AR (Vol. 445 Ref. 7593).

cigarette." Although ARIEL was never commercialized, Brown & Williamson continues to develop and patent similar tobacco products to this day. Like RJR's development of Premier and Eclipse, Brown & Williamson and BATCO's development of these alternative tobacco products that deliver little more than nicotine shows that the companies regard cigarettes as, in effect, devices for the delivery of nicotine.

Third, BATCO launched efforts to find a nicotine analogue. A 1968 conference of BATCO researchers recommended:

In view of its pre-eminent importance, the pharmacology of nicotine should continue to be kept under review and attention paid to the possible discovery of other substances possessing the desired features of brain stimulation and stress-relief without direct effects on the circulatory system. 629

BATCO's interest in nicotine analogues led to a 1972 BATCO report that "concluded that substances closely related to nicotine in structure (nicotine analogues) could be important" because "[s]hould nicotine become less attractive to smokers, the future of the tobacco industry would become less secure." Thus, as with Philip Morris,

⁶²⁷ U.S. Patent No. 3,356,094, Ellis CD, Dean C, Hughes IW, assigned to Battelle Memorial Institute, Smoking Devices (Dec. 5, 1967), at C2:66-71 (emphasis added). See AR (Vol. 34 Ref. 571).

⁶²⁸ Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table*, at 5 (stating that "[O]ther tobacco industry patent activity by . . . Brown & Williamson illustrates extensive interest in the development of a superior nicotine delivery device with or without a tobacco base"). *See* AR (Vol. 531 Ref. 122).

Slade J, Bero LA, Hanauer P, et al., Nicotine and Addiction, the Brown & Williamson documents, Journal of the American Medical Association 1995;274(3):225-233, at 228. See AR (Vol. 528 Ref. 97).

⁶²⁹ Minutes of BATCO Research Conference at Hilton Head, SC (Sep. 24-30, 1968), at 3 (emphasis added). See AR (Vol. 31 Ref. 525-1).

⁶³⁰ Kilburn KD, Underwood JG (BATCO), Preparation and Properties of Nicotine Analogues (Nov. 9, 1972), at 1. See AR (Vol. 31 Ref. 524-1).

Brown & Williamson's nicotine analogue research demonstrated the company's intention to preserve the effects of nicotine on the brain in new tobacco products.

Collectively, the three areas of product development research related to nicotine delivery in the 1960's show Brown & Williamson's long-standing focus on delivering pharmacologically active doses of nicotine to smokers.

ii. Product Research and Development to Maintain Pharmacologically

Satisfying Doses of Nicotine while Lowering Tar. Documents in the administrative record indicate that BATCO's efforts in the 1970's coalesced around the objective of maintaining nicotine deliveries in lower-tar cigarettes. The minutes of a 1975 BATCO research conference, for instance, observed that "[o]nce again the need for normal nicotine low tar cigarettes which appeal to the consumer was identified." A year later, at a 1976

BATCO conference, the researchers predicted a "clear opportunity" for low-tar, normal-nicotine cigarettes "[p]rovided we can get smokers to dissociate tar from nicotine in their minds in terms of a possible health hazard." At another 1976 conference, the researchers stated:

[I]n that the 'benefits' of smoking appear to be related to nicotine, we can infer that the 'benefits' of smoking might disappear if cigarettes with low levels of nicotine became the norm . . 633

In conjunction with their efforts to develop cigarettes that were low in tar but maintained nicotine delivery, Brown & Williamson and BATCO conducted product

⁶³¹ Minutes of BATCO Group R&D Conference at Merano, Italy (Apr. 2-8, 1975), at 4 (emphasis added). See AR (Vol. 27 Ref. 379-1).

⁶³² Minutes of BATCO Group R&D Conference on Smoking Behaviour at Southampton, England (Oct. 11-12, 1976), at 8. See AR (Vol. 27 Ref. 379-2).

⁶³³ Id. at 4.

development research in the 1970's and 1980's to determine the dose of nicotine required to produce satisfying pharmacological effects in smokers. Project Wheat was central to these efforts. The multiyear project had two parts. In Part 1, the attitudes of over 1,000 smokers were surveyed to assess their "inner need" to smoke. 634 In Part 2, the smokers were asked to assess experimental cigarettes with different nicotine deliveries. 635 According to BATCO:

The purpose of the survey was to classify smokers into a number of categories showing distinct patterns of motivation, and different levels of so-called Inner Need, as a first step towards testing the hypothesis that a smoker's Inner Need level is related to his preferred nicotine delivery. 636

Project Wheat was thus designed to determine the optimum dose of nicotine delivered by cigarettes for individual smokers as a function of the strength of their "inner need" to smoke. BATCO researchers defined "inner need" as the smoker's use of cigarettes to relieve stress, aid concentration, control appetite, and relieve craving. 637 These are the characteristic pharmacological effects of nicotine. See section II.B., above. They also described "the 'inner need' dimension" as correlating "with the extent of inhalation, with the craving for cigarettes when these are not available, and with the

⁶³⁴ Wood DJ, Wilkes EB (BATCO), Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and their General Smoking Habits (Jul. 10, 1975), at 1. See AR (Vol. 20 Ref. 204-1).

⁶³⁵ Wood DJ (BATCO), Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need (Jan. 30, 1976). See AR (Vol. 20 Ref. 204-2).

⁶³⁶ Wood DJ, Wilkes EB (BATCO), Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and their General Smoking Habits (Jul. 10, 1975), at 1 (emphasis added). See AR (Vol. 20 Ref. 204-1).

⁶³⁷ Wood DJ (BATCO), Project Wheat (Jan. 10, 1974). See AR (Vol. 177 Ref. 2056).

difficulty which consumers anticipate in giving up smoking." Thus, a nicotine level that satisfies "inner need" is one that provides desired pharmacological effects.

According to the BATCO researchers, the hypothesis that "inner need" is related to nicotine delivery should be "seen as part of a general approach to the problem of designing cigarettes of increased consumer acceptance." They further explained: "In considering which product features are important in terms of consumer acceptance, the nicotine delivery is one of the more obvious candidates. . . . The importance of nicotine hardly needs to be stressed, as it is so widely recognised." 640

Project Wheat found that "[a]s predicted by the hypothesis, *High Need clusters* tend to prefer relatively high nicotine cigarettes, their optimum nicotine delivery being higher than that of Low Need clusters." Project Wheat also found that there was a conflict between smokers' concern for health, which led them to favor low-tar brands of cigarettes, and their "inner need" to smoke, which led them to seek higher nicotine levels. According to the project report:

Concern for the possible health risks of smoking influences consumers in the direction of trying low delivery brands....

However there is evidence of a conflict between concern for health and the desire for a satisfying cigarette, from which it follows that low tar brands would be much more widely accepted if their

⁶³⁸ Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives, 103d Cong., 2d Sess. 438 (Jun. 21 and 23, 1994) (emphasis added). See AR (Vol. 709 Ref. 3).

⁶³⁹ Wood DJ, Wilkes EB (BATCO), Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and their General Smoking Habits (Jul. 10, 1975), at 1. See AR (Vol. 20 Ref. 204-1).

⁶⁴⁰ Id. at 3 (emphasis added).

⁶⁴¹ Wood DJ (BATCO), Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need (Jan. 30, 1976), at 1 (emphasis added). See AR (Vol. 20 Ref. 204-2).

nicotine deliveries could be brought within the range required by groups of consumer[s]. ⁶⁴²

Most important, the project developed a model of the cigarette market that showed a "substantial potential" for cigarettes that attract smokers concerned about both their health and satisfying their "inner need" for nicotine. According to the project report:

A model of the market is now proposed in which two major determinants of the type of cigarette which best suits a smoker's requirements are Inner Need and concern for health. This model leads to the conclusion that there is a substantial potential for a range of cigarettes which at present is not available. These cigarettes range from some with low tar and medium nicotine deliveries to others with medium tar and high nicotine deliveries, and are visualised as attracting those smokers who combine above average Inner Need with above average concern for health. 643

A chart in the Project Wheat report showed the magnitude of this new potential market. According to the chart, over 40% of smokers want a cigarette with lower tar and higher nicotine than currently available.⁶⁴⁴

Project Wheat is persuasive evidence of the extensive product research and development by Brown & Williamson and BATCO to manipulate nicotine levels to provide pharmacologically active doses of nicotine. Project Wheat's "model of the market" showed the companies that there existed a significant market for cigarettes with low-tar levels but relatively enhanced nicotine levels.

Brown & Williamson and BATCO conducted additional research designed to correlate nicotine dose and pharmacological effects. For example, a 1980 BATCO Group

⁶⁴² Id. at 48.

⁶⁴³ Id. at 2 (emphasis added).

⁶⁴⁴ Id. at 50-51.

R&D report describes BATCO's successful effort to develop an improved method for measuring nicotine and its metabolites in the body. The method was developed to study the pharmacological effects of nicotine and their relationship to nicotine dose.

The report states that in some cases:

the pharmacological response of smokers to nicotine is believed to be responsible for an individual's smoking behaviour, providing the motivation for and the degree of satisfaction required by the smoker.

[W]here the causal relationship between nicotine and individual biochemical physiological or psychological responses are to be investigated, accurate information regarding nicotine dose is essential.⁶⁴⁵

A related study was designed to provide an animal model that would allow BATCO to estimate human nicotine doses and to aid in understanding the relationship between the dose of nicotine delivered by cigarettes and smokers' choice of particular brands.⁶⁴⁶

A session on "Nicotine Dose Estimation" at BATCO's 1984 Smoking Behaviour-Marketing Conference was intended "to review the current status of plasma/urinary measures . . . of nicotine dose and to identify the significance for the smoker and product design." That same year, BATCO described its proposed research agenda for 1985-1987 as including studies "to establish the *minimum dose of smoke nicotine that can provide pharmacological satisfaction* for the smoker."

⁶⁴⁵ Read GA, Anderson IGM (BATCO Group R&D), Method for Nicotine and Cotinine in Blood and Urine (May 21, 1980), at 2-3. See AR (Vol. 59 Ref. 235).

⁶⁴⁶ Read GA, Anderson IGM, Chapman RE (BATCO Group R&D), Nicotine Studies: A Second Report. Estimation of Whole Body Nicotine Dose by Urinary Nicotine and Cotinine Measurement (Mar. 3, 1981), at 9-10. See AR (Vol. 59 Ref. 234).

⁶⁴⁷ Proceedings of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session II, Montreal, Canada (Jul. 9-12, 1984) (slide), at BW-W2-02641. See AR (Vol. 23 Ref. 305).

⁶⁴⁸ BATCO Group R&D Research Programme, 1984: Proposed revisions for 1985-87, Research Conference, Southampton, England (Sep. 1984), at 2 (emphasis added). See AR (Vol. 22 Ref. 280).

As described below, Brown & Williamson and BATCO pursued three different strategies in the late 1970's and 1980's for reducing tar deliveries in cigarettes while maintaining adequate nicotine deliveries.

Blending and "Y-1." One approach to reducing tar levels while iii. maintaining adequate nicotine levels is through blending. As noted above in section II.C.3.c.i., BATCO researchers first investigated this approach 30 years ago, when they recommended "alteration of blends" as one way to obtain "maximum nicotine for minimum tar." By 1976, they had concluded that "there would appear to be a forthcoming demand for high nicotine tobaccos" in view of the interest in increasing the nicotine/tar ratios in low tar cigarettes.650

By the late 1970's, Brown & Williamson had begun a decade-long effort to develop a high-nicotine flue-cured tobacco plant that came to be named "Y-1." As described in the Jurisdictional Analysis, the Agency found that the company used conventional and advanced genetic breeding techniques to develop a commercially viable plant that had almost twice the nicotine content of domestically grown varieties of flue cured tobacco. See 60 FR 41700-41702. Whereas typical domestic varieties of tobacco contain between 2.5% to 3.5% nicotine, Brown & Williamson's patent for Y-1 indicated that the company had succeeded in raising the nicotine level to about 6% by weight.⁶⁵¹ Brown & Williamson achieved this objective by cross-breeding commercial varieties of

⁶⁴⁹ Griffith RB (BATCO), Report to Executive Committee (Jul. 1, 1965), at 2. See AR (Vol. 27 Ref. 377).

⁶⁵⁰ Minutes of BATCO Group R&D Conference on Smoking and Behaviour at Southampton, England (Oct. 11-12, 1976) at BW-W2-02311 (emphasis added). See AR (Vol. 27 Ref. 381).

⁶⁵¹ U.S. Patent application, Fisher PR, Hardison HA, Bravo JE, New Variety of Tobacco Plant, assigned to Brown & Williamson Tobacco Corp. (1991), at 1. See AR (Vol. 68 Ref. 14).

tobacco with *Nicotiana rustica*, a wild tobacco variety that is very high in nicotine but is not used in commercial cigarettes because of its harshness.

Brown & Williamson had Y-1 made into a male sterile plant, a technique that ensures that when the plant is grown it will not produce seeds that can be appropriated by others. Brown & Williamson grew the plant in Brazil. The Agency further found, and the company does not dispute, that Y-1 was eventually used in five different brands of cigarettes in 1993, and that as of mid-1994 Brown & Williamson still had 3.5 million to 4 million pounds of additional Y-1 in storage.

The purpose of Y-1 was to develop a high-nicotine tobacco that could be used as a "blending tool" so that products could be designed that were lower in tar but not lower in nicotine. Although Brown & Williamson asserts that it never used Y-1 in commercial cigarettes to raise nicotine/tar ratios, the company does not dispute that its goal was to deliberately alter the traditional relationship between tar and nicotine. Indeed, Brown & Williamson implicitly concedes that the company used Y-1 to develop "prototypes" with increased nicotine/tar ratios and tested them on consumer panels. The development of Y-1 thus provides direct evidence of Brown & Williamson's intention to enhance nicotine deliveries.

⁶⁵² Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives, 103 Cong., 2d Sess. 18 (Jun. 21, 1994) (testimony of David Kessler). See AR (Vol. 709 Ref. 3).

⁶⁵³ Id. at 142 (testimony of Thomas Sandefur, chairman and CEO, Brown & Williamson).

⁶⁵⁴ Transcript of FDA Meeting with Brown & Williamson (Jun. 17, 1994), at 124-125. See AR (Vol. 28 Ref. 414).

⁶⁵⁵ Id. at 85-86.

⁶⁵⁶ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 32. See AR (Vol. 529 Ref. 104).